REMARKS

Applicants have amended the specification to add the heading and cross-reference information suggested by the U.S. Patent and Trademark Office. The claim for priority was made at the time the present application was filed, as reflected on the filing receipt. As such, this amendment does not constitute new matter and their entry is respectfully requested.

Claim 1 has been amended to make explicit that which was implicit, namely that the perforated substrate is coated without substantial occlusion of the perforations. This amendment is supported by original claim 1, as well as by page 1, lines 30 – 32 of the specification, and does not introduce new matter. Claims 16 – 19 and 21 have been rewritten as process claims, rather than as product by process claims. These amendments are supported by their respective original claims, and do not introduce new matter, and their entry is respectfully requested. Claims 39 – 42 have been rewritten in independent form, including the recitations of claim 38, without any product by process recitations, as claims 42 – 44. As such these claims do not introduce new matter and their entry s respectfully requested.

The Examiner indicated that two references disclosed in the Information Disclosure Statement, namely FR 2783412 and EP 0283651, were not considered because they were not accompanied by a translation or an English abstract. Applicants are submitting a Supplemental Information Disclosure Statement herewith. Reference BL is an Australian application which corresponds to FR 2783142. Reference BM is an English translation of the patent that issued in connection with EP 0283651, which was filed with the UK Patent Office as part of the procedure for bringing the issued patent into effect in the UK.

Applicants appreciate the Examiner's indication that claims 39 – 41 contain allowable subject matter.

Claims 1, 3, 5, 7 – 9, 12, and 16 – 18 were rejected under 35 U.S.C. §102(b) as being anticipated by von Bittera et al. (US 4,661,099).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The present invention is directed to a coated perforated substrate with a gel without substantial occlusion of the perforations as well as a method for making the substrate. This can be accomplished by employing a web coated with a coating having a surface energy lower than the liquid pregel mixture. This results in a coated perforated substrate without substantial occlusion of the perforations. In a preferred embodiment, only one side of the substrate is coated by a gel.

von Bittera does not disclose or suggest such a *perforated substrate or* method. The only substrates disclosed are *without* such perforations. Example 1, which the Examiner has pointed to, discloses a process for coating an elastic knitted fabric with a gel. However, von Bittera describes the resultant coated substrate as having an "adhesive layer of gel" (see col. 8, lines 15 – 16). This teaches that the gel layer is continuous and would occlude any perforations present in the elastic fabric. Thus, von Bittera does not disclose coating a perforated substrate without substantial occlusion of the perforations, as required by the amended claims, and there is no anticipation.

Accordingly, applicants respectfully submit that this rejection of the claims should be withdrawn.

Claims 16 – 18 and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by Brassington et al. (US 4,838,253).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The Examiner has indicated that the rejected claims were anticipated because the product of these claims was anticipated by the Brassington substrate, which is an aperatured material which is unoccluded by its silicone coating. While applicants disagree with the Examiner, these claims have been amended so that they are directed to a process, rather than a product. This obviates the rejection. Accordingly, applicants respectfully submit that this rejection of the claims should be withdrawn.

Claims 1 – 9, 12, 14, and 16 – 30 were rejected under 35 U.S.C. §103 (a) as being unpatentable over WO 97/42985 in view of Jensen (5,133,821).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

As explained by the Examiner, WO teaches a process of making a wound dressing, in which a layer of uncured gel mixture is placed on a plastic film, a layer of foam material is applied on the gel mixture with a roller, and then the gel mixture is cured using heat (page 9, lines 1 to 12).

The Examiner admits that WO does not teach the use of a web, as claimed in the present application.

Rather, WO proposes a range of options for preventing an excessively large number of

the pores from being occluded. However, none of these options is related to the construction of the underlying web (plastic film). For example, WO teaches that the control of occlusion of pores or holes in the foam can be achieved by (i) suitable selection of the gel mixture (ii) suitable selection of the pressure force, (iii) suitable selection of the quantity of gel mixture (iv) suitable selection of the time between applying the foam material and heating the layers, (v) suitable selection of the curing temperature (vi) suitable selection of the size of the pores in the foam material, and (vi) suitable selection of the viscosity of the gel mixture (page 9, lines 14 – 32). It is taught, for example, that "the gel mixture must be applied in a layer of such thinness as to ensure that an excessively large number of the pores opening into the underside of the foam material will not be clogged or blocked by the gel coating. The viscosity of the gel mixture and the size of the pores in the foam material also influence the tendency of the mixture to penetrate into the pores" (page 9, lines 22 – 28).

In fact, because of the importance of the nature of the gel disclosed in WO, the skilled artisan would have no motivation to modify the web with a coating to have a surface energy lower than the surface energy of the liquid pregel mixture, as claimed in the present invention. As explained in the paragraph bridging pages 5-7, the key is the adhesive gel. For example, at page 5, lines 31-33 it is taught:

> The nature of the adhesive gel used in this intention differs totally from the nature of glues that are typically used to secure dressings...

A key feature is that the gel has a much lower than normal specific adhesiveness (page 6, lines 3 – 7). The gel material in WO is a silicone gel or similar hydrophobic gel (page 5, lines 8 – 16). It is taught that the gel is much softer and has a better "wetting ability" than other glues typically used in such wound dressings, resulting in a much lower specific adhesiveness (page 5, line 31 to

page 7, line 21). Because of the emphasis on a gel that has a much lower than normal specific adhesiveness, there can be no inherent motivation on the part of the skilled artisan to modify the web on which the gel is laid down. A significant concern with a gel having very low specific adhesiveness is how to maintain effective adhesion between the gel and the web. An advantage of the gel is that the dressing can be repeatedly removed from the skin. Thus, the skilled artisan would be taught to do nothing to weaken the bond between the gel and the substrate. It would be counterintuitive for the skilled artisan, reading WO, to actively seek to reduce effective adhesion still further. In view of the extensive discussion in WO about a wide range of different options for preventing an excessively large number of the pores from being occluded, none of which relates to the web, nothing teaches or suggests that there is any benefit in modifying the web, as claimed in the present invention. Lowering the surface energy of the web in contact with a gel which itself is of very low surface energy (which correlates with specific adhesiveness) would run the serious risk of insufficient adhesion between the two parts, so that the gel would be at risk of undesired movement on the web.

Furthermore, because the WO gel has a relatively very low surface energy (specific adhesiveness), to produce a web having a surface energy lower than the gel would in fact be technically extremely difficult.

Therefore, WO actually teaches away from lowering the surface energy of the web.

The Examiner has alleged that the combination of WO and Jensen teaches the reduction of the surface energy of the web, with Jensen providing motivation to modify the WO process to generate the present invention. However, the combination of Jensen and WO in no way teaches the claimed invention for the following reasons. As explained above, WO teaches away from changing the web.

Jensen, in contrast, is directed to improving the efficiency of the method for making contoured wound dressings. Jensen describes a continuous, substantially in-line process for making contoured dressings stating:

> It is believed that a reduction in energy requirements along with the increased production output will significantly reduce the cost of making this highly desirable wound dressing." (col. 1, lines 48-51).

This in no way suggests that one would improve the adhesiveness with WO type of gel. Indeed, Jensen uses a hydrocolloid adhesive. The Jensen process is primarily directed to conventional hydrocolloid gels, not to the specialized, very low specific adhesiveness gels of WO. Jensen does not even mention the specialized gels of WO. Thus, there is nothing to suggest the combination except the application of impermissible hindsight reconstruction. Indeed, about five years passed with the references out there and no one combined them.

The use of low specific adhesive gels such as those disclosed in WO in conjunction with the release web of Jensen would thought to be associated with a risk of undesired loss of adhesive traction between the layers. The adhesive traction is at the heart of the Jensen invention. Thus, the skilled artisan would have no motivation to combine these two approaches, given the risk of decreased adhesion.

Additionally, Jensen is concerned with preparing contoured wound dressings, where one of a pair of rollers is shaped to provided a contoured face to the finished wound dressing product (see, for example, Figure 4 and the associated description). The passage of a laminated web through such irregularly shaped roller pairs can meet with significant resistance. To overcome this problem, Jensen teaches the use of a thin release web for the laminate adjacent the hydrocolloid adhesive assists in reducing any resistance and protects the adhesive and the rollers.

The purpose of the "release web" in the Jensen process is described as follows:

> The thin release web 40 is made of a material having a release coating on at least one of its surfaces. It is preferred that the thin release web 40 be of a silicone release paper with its treated or release side facing and contacting the adhesive layer 26. The thin release web 40 provides a means for allowing the first major surface 30 of the adhesive layer 26 to be contoured without any transfer of hydrocolloid adhesive to the first contouring roller 48. The thin release web 40 also minimizes the friction generated during the contouring of the adhesive 26 by the action of the rollers 50 and 52" [col. 3, lines 53-64] [emphasis added]

It is clear from this description that the purpose of the Jensen release web is simply to protect the adhesive layer and the rollers of the apparatus, to achieve an efficient contouring process in which friction is reduced as the laminate moves through the contouring rollers of the apparatus. There is nothing that in any way suggests that a low surface energy web can enable the coating of the perforated substrate without substantial occlusion of the perforations.

In summary, Jensen in no way suggests that its release web could be adapted to address the completely different technical challenges posed by a perforated substrate. Jensen provides no motivation to use a web having a lower surface energy than the surface energy of the pre-gel adhesive, as in WO. The use of the release web in Jensen was for an entirely different purpose, and would have offered no expectation of an alternative way of controlling over-occlusion of the perforations of the substrate in the WO process. Jensen uses a completely different gel. The only way one would combine these references is to use impermissible hindsight reconstruction.

Accordingly, applicants respectfully submit that this rejection of the claims should be withdrawn.

Claims 1 – 4, 7 – 10, 12 – 17, and 24 – 31 were rejected under 35 U.S.C. §103 (a) as being unpatentable over Cheong (US 5,352,508) in view of Jensen.

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

Cheong describes a process for coating a hydrophilic tacky resin on a net wound dressing substrate, leaving the majority of the apertures in the net substrate unoccluded. As admitted by the Examiner, the resin is applied to coating rollers from a bath, and is then coated onto the substrate, which is then heated to cure the resin. Like WO, Cheong is concerned with potential over-occlusion of the apertures of the net substrate. However, also like WO, Cheong does not disclose the use of a web.

Instead, Cheong (column 5, lines 52 – 58) refers to the optional use of release sheets to laminate the coated substrate. The purpose of these release sheets is apparently the conventional one of protecting the adhesive structure in the often extended period between initial coating of the substrate and subsequent use of the coated substrate in the manufacture of the finished dressings.

The Examiner while acknowledging that Cheong does not teach a relatively low surface energy web on which the gel is applied during the manufacturing process, alleges that such a modification would have been obvious in view of Jensen.

However, as with the WO, the Examiner is using impermissible hindsight reconstruction to combine Jensen with Cheong, to argue that it would have been obvious to adapt the release web of Jensen with a low surface energy coating to solve the problem of producing a coated perforated substrate.

As explained above, the purpose of the release web in Jensen has nothing to do with that. Rather, it is to assist the contouring of the adhesive/substrate structure, and to minimize the friction generated during the contouring of the adhesive by the action of the rollers.

Cheong, like the WO, teaches the following with respect to avoiding excessive occlusion of pores:

> It will be appreciated that the relative amounts of reactants, the total mass of reaction mixture the mixing time the method of mixing and the temperature of the reaction will need to be selected so as to produce a reasonable gel time. If the gel time is too short, it may be impossible to coat the resin onto the substrate, or the resin may occlude substantially all of the apertures in the net. If the gel time is too long the resin may not completely encapsulate the net substrate and may form into drops on the substrate. [col. 4, lines 30 - 40]

Therefore, Cheong, like WO, focused on controlling the nature of the liquid pregel and the amount of liquid pregel applied to the substrate. There was absolutely no suggestion or appreciation that the problem of potential over-occlusion of the apertures could in any way be dealt with by the much simpler and less complex method found by the present inventors.

As explained in detail above, Jensen did not offer the solution in a way that would teach or suggest to these of ordinary skill in the art that the web could be used. There is no motivation to combine Jensen with Cheong, because the problem addressed by Jensen (the efficiency of a contouring process) is too far removed from the problem addressed by Cheong (over-occlusion of apertures). The use of the release web in Jensen was for an entirely different purpose, and would have offered no expectation of an alternative way of controlling over-occlusion of the perforations of the substrate in the Cheong process.

Indeed, there is absolutely no suggestion in Cheong that a contoured dressing is intended or in any way desired. It is taught against. At column 6 lines 8 to I 3, Cheong states that the dressings of his invention are "very conformable because the net substrate is pliant and because the coated resin does not significantly reduce this pliancy. They can therefore be easily applied to any area of the body, in particular areas such as fingers, elbows and knees which are irregular in shape and are often moved." Clearly Cheong is envisaging pliant and conformable dressings

and not contoured dressings.

Accordingly, applicants respectfully submit that this rejection of the claims should be withdrawn.

Claims 11 and 32 – 38 were rejected under 35 U.S.C. §103 (a) as being unpatentable over Cheong (US 5,352,508) in view of Jensen in further view of Kundel (US 5,674,346).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

The Examiner contends that claims 11 and 32 – 38 are obvious in view of the combination of Cheong, Jensen and Kundel. As explained above, the combination of Cheong and Jensen is not proper. Kundel does not overcome their deficiency.

Instead, in the passage bridging columns 5 and 6, Kundel merely states generally that porous or mesh-like layers about which the hydrogel polymerises may be incorporated into the hydrogel layer for the purpose of strengthening the laminate. No details are offered as to how that result might be achieved, let alone achieved without substantial occlusion of perforations or even whether it is desirable to avoid substantial occlusion of perforations.

Accordingly, applicants respectfully submit that this rejection of the claims should be withdrawn.

In re application of:	Munro et al.		
Serial No.:	10/004,315	Group No.:	1616
Filed:	October 23, 2001	Examiner:	Gollamudi

In view of the foregoing, applicants respectfully submit all claims are in condition for allowance. Early and favorable action is requested.

Respectfully submitted,

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